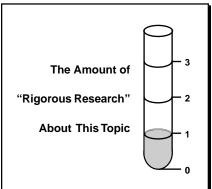


National Institutes of Health National Center for Complementary and Alternative Medicine (NCCAM) NCCAM Clearinghouse



- 3 Extensive Research: Numerous high-quality, scientific studies have been done, including clinical trials and other research published in major peer-reviewed journals. Reliable scientific information is available.
- 2 —Some Research: Some good quality, scientific studies have been published in peer-reviewed journals. Some reliable scientific information is available.
- 1 —Limited Research: A small number of scientific studies have been done, but few have been published in peer-reviewed journals. Some scientific information may be available.
- 0 —No Research: No scientific studies have been done. No scientific information is available.

Notes:

The above levels of research are based on the amount of published, rigorous clinical research conducted or sponsored by the NCCAM, other Institutes and Centers of the NIH, and other biomedical research institutions in the United States and internationally.

Treatments described in this publication are experimental. Always discuss any new treatment options with your health care provider.

See the last page for more information about the levels of science listed above.

Hepatitis C: Treatment Alternatives

Hepatitis C is a serious communicable (contagious) disease of the liver that is caused by the hepatitis C virus (HCV). Hepatitis C and its implications were identified only recently. There still is much to learn about the disease, the virus that causes it, and treatment options—both conventional and alternative.

About 3 million Americans are infected with HCV, and many of them do not even know they have it. Other forms of viral hepatitis usually resolve without treatment. But most people with HCV—85 percent—develop chronic (frequent or long-lasting) hepatitis C. The majority of people infected with HCV show no symptoms for up to 20 to 30 years. During that time, though, the infection may be slowly damaging the person's liver.

The virus can be found in a number of organs of the body. However, the infection is spread mainly by contact with the blood of an infected person. Once a person is infected, the body's immune (disease-fighting) system cannot combat the virus very well.

Most people with chronic hepatitis C develop long-term

liver disease, which interferes with the liver's ability to work properly. Some patients eventually develop cirrhosis (scarring of the liver); some get liver cancer; and some even die from liver disease.

Repeated injections of regular ("conventional") drugs, like interferon, currently available to treat chronic hepatitis C get rid of the virus only in approximately 30 to 40 percent of infected people. In addition, these drugs can produce unbearable side effects. So, many people are looking to complementary and alternative therapies for help.

Alternative Care

No complementary medicine or alternative medicine therapies have been scientifically proven to cure or even ease symptoms of hepatitis C.

However, some people are turning to herbs for relief. They use herbs either to help with hepatitis itself or to deal with side effects of interferon. These harmful side effects can include: sudden hearing loss; anemia and other forms of low blood cell counts; headaches; heart, eye, liver, or kidney problems; and disorders of the mind,

including depression. Among potential herbal therapies (including licorice root, ginseng, ginger, and St. John's wort) for hepatitis C, the most promising alternative treatment seems to be the herb commonly called milk thistle.

Preliminary studies in animals show that milk thistle may help protect the liver from injury by a variety of toxins ("poisons" such as drugs, viruses, alcohol, radiation, and poisonous mushrooms) and limit the damage from them.^{1,2} To date, the most reliable, and also quite preliminary, studies on people show that milk thistle does not cure liver disease, but that it may improve the way the liver works in patients with cirrhosis.¹ However, there is no current evidence to indicate that milk thistle directly affects HCV.

In Germany, where many herbs are regulated and prescribed like drugs, health authorities have approved milk thistle as a complementary treatment (given in addition to conventional drugs) for cirrhosis, hepatitis, and similar liver conditions.² But a great deal of research still is needed before this alternative therapy could be considered a standard treatment option in the United States.

Milk Thistle

Milk thistle originally is from Europe, but now it also is grown in the United States. Its scientific name is *Silybum marianum*. The ingredient that experts believe is responsible for its medicinal qualities is called silymarin. Silymarin is found in the fruits of the milk thistle plant. Studies in animals have shown that this active ingredient promotes the following activities:

Liver Cell Growth—Silymarin appears to promote the growth of some types of cells in the liver.^{1,2}

Antioxidation—Silymarin may be an effective "antioxidant," which means it may help fight a destructive chemical process in the body known as "oxidation." In oxidation, harmful substances

produced in the body (called free radicals) can damage cells. Some studies suggest that silymarin can prevent these substances from damaging liver cells.^{1,3,4}

Antihepatotoxic Activity—Studies suggest that silymarin can block various types of toxins from entering and injuring liver cells.^{1,2,5}

Inflammation Inhibition—Silymarin is thought to prevent inflammation (swelling) of the liver; this may be described as displaying anti-inflammatory properties.¹

Milk thistle is not used to prevent HCV from causing liver disease. Rather, it is used with the hope that it would minimize the damage to the liver that HCV can cause.

Studies of Milk Thistle in People

Although studies in animals provide a good deal of information on potential new treatments, studies in humans are needed before it can be determined if these therapies are appropriate, safe, and effective in people. The most rigorous type of study to establish a scientific basis for use of a new therapy in people is a randomized, double-blind, placebo-controlled (RDBPC) trial.

Although not focused primarily on HCV disease, the most relevant existing research data regarding milk thistle's use as a therapy for hepatitis comes from two RDBPC trials of silymarin's effects on cirrhosis.¹ The two studies produced conflicting results.

The first, reported in 1989, examined 170 patients with cirrhosis from various causes, including alcohol abuse.⁶ Approximately half (87) of the patients received silymarin (140 milligrams 3 times a day for 2 years). The others (83 patients) received a placebo. Because 24 patients dropped out of the study, a total of 146 patients (73 in each group) finished the 2-year study.

Important Terms

Active Treatment

The treatment being tested by the experiment.

Alternative Medicine

Medical systems, therapies, and techniques that mainstream Western (conventional) medicine does not commonly use, accept, study, understand, or make available. Alternative medicine includes practices usually used instead of conventional medical practices. Alternative health care practices include a vast array of treatments and beliefs, which may be well-known, exotic, mysterious, or even dangerous. They are based on no common or consistent philosophy or school of thought. A few of the many alternative medicine practices include the use of acupuncture, homeopathy, herbs, therapeutic massage, and traditional oriental medicine to promote well-being or treat health conditions.

Complementary Medicine

Alternative medical systems used in conjunction with or in addition to conventional medicine to further promote health. For example, a person may use herbal remedies to ease some of the side effects, such as nausea, of certain conventional drugs.

Controls

Patients who do not receive the treatment being studied; the experimental group is compared to the control group to objectively evaluate the treatment's effectiveness.

Double-Blind

A type of study in which neither the participants nor the doctors giving the treatments know who is getting the active treatment and who is getting the placebo.

Liver

A large gland in the upper abdomen that is essential to life. Important liver functions include: helping the body produce or make use of the fats, sugars, proteins, vitamins, and most other compounds it needs; and reducing the ill effects of poisons, such as alcohol and nicotine, in the body.

Placebo

A presumably pharmacologically inactive or "fake" treatment. If in the form of a pill, a placebo sometimes is referred to as a "dummy pill" or "sugar pill."

Placebo-Controlled

A type of study of usually one group of subjects to distinguish the specific and nonspecific effects of the active treatment.

Randomized

Study participants are assigned without bias to particular arms of a study.

Side Effects

Unintended, and usually undesirable, reactions that result from a treatment.

Virus

A tiny organism that can only grow in the cells of an animal or a person. Several hundred viruses have been found to cause diseases in people.

The doctors in this study noted that the number of patients who died in the 4 years after the study was 31 percent lower in the group that received the silymarin than in the group of patients who received the placebo. The beneficial effects of silymarin were especially seen in the patients who had cirrhosis as a result of alcohol abuse. The doctors did not report that any patients experienced side effects from silymarin treatment.

A more recent RDBPC trial, however, did not find silymarin to have any significant benefits for patients with cirrhosis.⁷ In this study, reported in 1998, doctors examined 200 patients with cirrhosis caused by alcohol abuse. Approximately half (103) of the patients received silymarin (150 milligrams 3 times a day for 2 years). The other half (97) received a placebo. A total of 125 patients (57 in the treatment group and 68 in the placebo group) finished the 2-year study. To measure effectiveness, the doctors measured (1) time to death and (2) the worsening of the disease.

Survival was similar in both the silymarin and placebo groups, and silymarin did not seem to improve the course of the disease in the treatment group. The doctors who performed the experiment did not note side effects in any of the patients.

Although small, one randomized controlled trial on hepatitis patients suggests that a specific component in silymarin may be beneficial in managing chronic hepatitis. In this study, reported in 1993, 10 patients with chronic hepatitis were assigned to the treatment group and 10 others were assigned to the placebo group. The treatment group received 240 milligrams of silybin, a component of silymarin, two times a day for 1 week. The results of tests that measure how well the liver is functioning showed significant improvement in the treatment group, suggesting that silybin may help treat chronic hepatitis.

Milk thistle in the treatment of liver disease needs to be studied further. Fortunately, negative side effects have not yet been reported, and this herbal therapy may be much less expensive than conventional drug therapies. Yet, it should be mentioned that conventional therapies have been proven to work in a substantial portion of patients.

Because milk thistle does not dissolve well in water, the herb is not effective in the form of a tea. It currently is marketed in the United States as a dietary supplement in the form of capsules containing 200 milligrams of a concentrated extract with 140 milligrams of silymarin.

Other Herbs That May Help

Licorice Root—Herbalists use tea made with licorice root to manage some of the effects hepatitis has on the liver. The scientific name for licorice root is *Glycyrrhiza glabra*, and its active component is called glycyrrhizin. Studies suggest that licorice root displays antiviral and anti-inflammatory properties.⁹

Licorice root does come with a warning, however. If taken regularly (more than 3 grams of licorice root a day for more than 6 weeks, or more than 100 milligrams of glycyrrhizin a day), this herb can cause the following conditions in some people: high blood pressure, sodium and water retention, low potassium levels in the bloodstream, and disturbance of an important electrolyte balancing system in the body.

Signs and symptoms of excessive licorice root consumption may include headache, sluggishness, puffiness and swollen ankles, and even heart failure or cardiac arrest (when the heart suddenly stops beating).¹⁰

Glycyrrhizin has been used in Japan for more than 20 years as a treatment for chronic hepatitis.^{9,11} In a 1998 review¹¹ of several randomized controlled trials, researchers reported that treatment with glycyrrhizin is effective in easing liver disease

in some people. Several of the trials reviewed indicated improvements in liver tissue that had been damaged by hepatitis. Some of them also showed improvements in how well the liver does its job.

A great deal of scientific research still is needed to learn if these alternative therapies are safe and effective in people.

A 1997 experiment suggested that glycyrrhizin also may help prevent the development of liver cancer in patients with chronic hepatitis C.¹² The use of glycyrrhizin as a complementary therapy (in addition to conventional use of interferon drugs) has been studied, but no significant benefit has been found yet.^{13,14}

Ginseng—Tests on animals and on human tissues suggest that ginseng may help the body's disease-fighting and glandular systems. Tests in small animals also suggest that ginseng may help improve the way the liver works and reduce damage to liver tissue caused by hepatitis and similar conditions. However, a search of the current literature shows no studies in people that test ginseng's helpfulness for hepatitis. Only one study, conducted in Italy, shows that ginseng may be helpful for elderly people with liver conditions similar to hepatitis. ¹⁸

There are two true ginsengs—American ginseng (*Panax quinquefolius*) and Asian ginseng (*Panax ginseng*), which includes Chinese, Japanese, and Korean ginseng. Siberian ginseng (*Eleutherococcus senticosus*) is not a true ginseng.^{1,19} It is hard to get authentic ginseng products. Companies that market herbs for sale have poor quality control, so the quality of the different brands varies widely. A 1990 analysis of 54 available ginseng products revealed that 85 percent of them contained little or no ginseng at all!¹⁹ Ginseng most often is taken as a tea.

Herbs That May Ease Interferon's Effects

Ginger—For 2,500 years, the Chinese have used ginger (*Zingiber officinale*) to treat nausea.¹ Some, but not all, research studies confirm that ginger may reduce nausea.¹ This herb may relieve nausea and vomiting caused by interferon drug therapy in some patients with hepatitis C. Ginger generally is recognized as safe and is not known to cause any serious side effects. Ginger is relatively inexpensive and readily available. It most commonly is taken in the form of a tea.

St. John's Wort—Some patients with hepatitis C take the herb St. John's wort (*Hypericum perforatum*) to treat depression caused by interferon drug therapy. Although St. John's wort is not a proven treatment for depression, studies have shown that it does have antidepressive effects over the short term. Although research largely has been done using capsules of this herb, St. John's wort also is taken as a tea. There is no proof yet that St. John's wort is effective and safe over the long term.

St. John's wort does not require a prescription, and it is less expensive and may have fewer side effects than prescription antidepressant drugs.²⁰ Tests in people reveal it may cause side effects such as fatigue, dry mouth, dizziness, digestive tract symptoms, and increased sensitivity to sunlight.

If You Have Hepatitis C

- Get an accurate diagnosis from your doctor. Hepatitis C infection can be diagnosed only by using sophisticated blood tests available to all doctors.
- Tell your doctor about all of the medications you are taking, even any over-the-counter drugs or herbs or other alternative therapies you may be using. Because the liver plays a key role in processing drugs, alcohol, and toxins in the bloodstream, medications, alcoholic beverages, and certain herbs can make the disease worse.

- Consider being vaccinated against hepatitis A and B.²¹ Unlike hepatitis A and B, previous infection with HCV does not make you immune to it in the future.²¹ Infection with HCV also does not prevent you from becoming infected with other types of hepatitis (hepatitis A, B, D, E, and G).
- Do not try to treat the disease yourself.
- Do not donate blood.
- Do not drink alcohol, because it can further damage your already diseased liver.
- Do not share needles if you use injection drugs.

For More Information

For more information about hepatitis C, you may want to contact the following organizations:

- American Liver Foundation
 1-800-465-4837 (1-800-GO-LIVER) (Toll-Free)
 http://www.liverfoundation.org (Web Site)
- Hepatitis Branch, Centers for Disease
 Control and Prevention
 1-888-443-7232 (1-888-4HEPCDC) (Toll-Free)
 http://www.cdc.gov/ncidod/diseases/hepatitis
 (Web Site)
- Hepatitis Foundation International 1-800-891-0707 (Toll-Free) http://www.hepfi.org (Web Site)
- National Digestive Diseases Information Clearinghouse 301-654-3810 http://www.niddk.nih.gov/health/digest/nddic.htm (Web Site)

For more information about alternative therapies for hepatitis C, you may wish to contact the following organizations:

- American Botanical Council http://www.herbalgram.org (Web Site)
- Herb Research Foundation 303-449-2265 (Telephone) http://www.herbs.org (Web Site)

For more information about complementary or alternative medicine, contact the NCCAM Clearinghouse by telephone, mail, e-mail, or fax:

NCCAM Clearinghouse
P.O. Box 8218
Silver Spring, MD 20907-8218
1-888-644-6226 (Toll-Free, TTY-TDY, and Fax-On-Demand)
1-301-495-4957 (Fax)
nccamc@altmedinfo.org (E-Mail)
http://nccam.nih.gov (NCCAM Web Site)

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More About the Levels of Research on Page 1

The Amount of

"Rigorous Research"

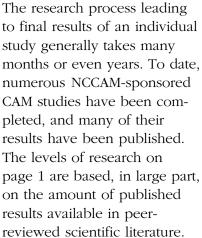
About This Topic

The treatments described in this publication are experimental. Researchers have not yet found out if and how they may be used safely and effectively in most people. If you are considering any treatment, always first discuss the treatment with your health care provider.

The term "scientific studies" used in the levels of research refers to quality research conducted in people by scientists sponsored by the National Center for Complementary and Alternative Medicine (NCCAM), other Institutes and Centers of the National Institutes of Health (NIH), and additional biomedical research institutions in the United States and internationally.

NIH's NCCAM produced this publication to give you information about complementary and alternative medicine (CAM) practices. The NCCAM is an advocate for quality science,

rigorous and relevant research, and open and objective inquiry into which CAM practices work, which do not, and why. As part of its congressional mandate, the NCCAM funds many studies of CAM practices.



Because there is no published research conducted in the United States on CAM and hepatitis C to report at this time, the information provided in this publication is based on studies done outside the United States.

Inclusion of a treatment or resource in this fact sheet does not imply endorsement by the National Center for Complementary and Alternative Medicine, the National Institutes of Health, or the U.S. Public Health Service.

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